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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,195	05/12/1999	ERIC THIBAULT	410.016	5847

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EXAMINER
RIMELL, SAMUEL G

ART UNIT	PAPER NUMBER
2166	

DATE MAILED: 04/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/308,195	THIBAULT ET AL.	
	Examiner	Art Unit	
	Sam Rimell	2166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

SAM RIMELL
PRIMARY EXAMINER
AU 2166

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1: The phrase "the processing of information" lacks antecedent basis". The phrase "the management of quality" lacks antecedent basis and is indefinite. The phrase "sequential and conditional validation" is indefinite. The word "buy" appears to be a grammatical error. The phrase "the passing from one validation step" lacks antecedent basis. The phrase "the following validation step" lacks antecedent basis. The phrase "the results of the processing" lacks antecedent basis. The phrase "the data collected in the different validation steps" lacks antecedent basis. The phrase "the standard operating procedure and/or a list of the anomalies" lacks antecedent basis.

Claim 2: The phrase "the input of the validation password" lacks antecedent basis.

Claim 3: The phrase "the screen page which provides the process operator" is vague and confusing. The phrase "a stage of process number i" is confusing.

Claim 5: The phrase "the exit from certain stages" lacks antecedent basis. The phrase "the screen pages" is indefinite.

Claim 8: The phrase "the results of control tests carried out on each batch of samples" lacks antecedent basis.

Claim 9: The phrase "and/or a list of the anomalies detected" is indefinite.

Claim 10: The phrase "designed to execute management tasks of a preparation laboratory number n within this laboratory" is vague and indefinite.

Claim 11: It is not clear whether the claim is limited to all, some, or just one of the recited entities.

Claim 12: The phrase "the information processing system" lacks antecedent basis.

Claim 13: The phrase "the information processing system" lacks antecedent basis.

Claim 14: The phrase "the quality management system" lacks antecedent basis.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over MDS Health Group Limited, hereafter referred to as "MDS".

Claim 1: MDS discloses functional steps of sequential and conditional validation, as shown in the flow chart of FIG. 2 and FIG. 5. Any step in the flow chart in which a decision must be made reads as a step of conditional validation. All the steps in the flow chart are sequential steps. Based on the data collected, a certification is issued at the last step (FIG. 10 illustrating release of results). Any anomalies detected are reported in the result release of FIG. 10.

MDS only differs from claim 1 in that it does not disclose re-injecting cells. However, Examiner takes Official Notice that it is well known in the art to perform dialysis treatment where blood cells are removed from the body and subsequently re-injected. It would have been obvious to one of ordinary skill in the art to modify MDS to be used in the well known environment of a dialysis treatment, where some of the blood cells removed from the body are

sampled and tested, and the remaining untested cells are returned to the body. This is a conventional protocol used in dialysis treatment to test the effectiveness of the treatment.

Claim 2: FIG. 3 illustrates the requirement for a password input.

Claim 3: FIG. 3 is the certification screen page.

Claim 4: FIG. 7i shows a coded identification field in the top left corner (field for barcode number).

Claim 5: The step of printing certain screen pages, particularly the results screen page (FIG. 10) is well within the scope of the MDS reference.

Claim 6: Each test culture constitutes a "kit". The transfer of the kits to the testing laboratory is monitored by attributing a bar code to each kit so that each kit can be recorded as existing in the laboratory (See top left corner of FIG. 7(a) where bar codes are recorded for each test culture.

Claim 7: Modifying the test kits of MDS to be cytapheresis pouches would have been obvious to one of ordinary skill in the art as a choice of design.

Claim 8: FIGS. 2 and 5 illustrate the process for carrying out control tests.

Claim 9: Claim 9 corresponds to the features recited in claim 1.

Claim 10: Any task defined in FIGS 2 or 5 constitute a management task.

Claim 11: The laboratory information system of MDS is connected to a network of laboratory computers (FIG. 1).

Claim 12: The dialysis procedure as described with respect to claim 1 is a form of cell therapy.

Claim 13: Using the cell testing system of MDS in association with gene therapy as opposed to dialysis would have been obvious to one of ordinary skill in the art as a choice of design.

Claim 14: Any usage of a system constitutes training on that system.

Remarks

Although applicant's amendments have eliminated some of the bases of rejection under 35 USC 112, many of the rejections remain. Examiner has examined the present claims in view of the closest prior art reference. This office action is not made final.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

Sam Rimell
Primary Examiner
Art Unit 2166